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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/783,994	02/20/2004	Ellis L. Reinherz	1062.2002-004	4354

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HAMILTON, BROOK, SMITH & REYNOLDS, P.C.  
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CONCORD, MA 01742-9133

EXAMINER
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LONG, SCOTT

ART UNIT	PAPER NUMBER
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1633

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/26/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.



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UNITED STATES DEPARTMENT OF COMMERCE

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APPLICATION NO./ CONTROL NO.	FILING DATE	FIRST NAMED INVENTOR / PATENT IN REEXAMINATION	ATTORNEY DOCKET NO.
10/783,994	20 FEB 2004	REINHERZ, ELLIS	1062.2002-004
			EXAMINER
			SCOTT LONG
		ART UNIT	PAPER
		1633	20070312

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner for Patents

Petition to Accept Color Drawings/Photographs (color drawings of Figures 2 and 8) is ACCEPTED.

Joe Winters  
A01633

**Office Action Summary**

Application No.

10/783,994

Applicant(s)

REINHERZ ET AL.

Examiner

Scott D. Long

Art Unit

1633

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 23 January 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) 9 and 13-38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8 and 10-12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Claim Status***

Claims 1-38 are pending. However, claims 9 and 13-38 are withdrawn from further consideration by the Examiner, pursuant to 37 CFR 1.142(b), as being drawn to non-elected inventions, there being no allowable generic or linking claim. Claims 1, 4, 7, 8 and 10 are amended. Claims 1-8 and 10-12 are under current examination.

### ***Sequence Compliance***

Sequence Listing and CRF have been received and are acknowledged by examiner. A statement that the Computer Readable Form (CRF) and the Sequence Listing are identical has been submitted and is acknowledged by examiner.

The examiner thanks the applicant for supplying a courtesy copy of preliminary amendments wherein the Brief Description of the Drawings recite appropriate sequence identifiers. The examiner withdraws his objection to Figure 2, based on non-compliance with sequence compliance rules.

### ***Priority***

This application claims benefit from PCT/US02/08288 (filed 14 March 2002) which claims benefit from provisional US Application 60/314,046 (filed 22 Aug 2001) and from provisional US Application 60/322,993 (filed 18 Sept 2001). The examiner has

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reviewed the specification of provisional US Application 60/314,046 (filed 21 Aug 2001) and concluded that all the subject matter of the elected invention of the pending claims is included therein. Therefore, instant application has been granted the benefit date, 22 August 2001, from the application 60/314,046.

### ***Drawings***

The examiner acknowledges the applicant's request to grant the Petition to Accept Color Drawings. Please find enclosed a copy of the granted petition signed and dated by the examiner's Supervisory Patent Examiner.

### ***Response to Arguments - Claim Objections***

The examiner withdraws his objection to claim 1. The amendments to claim 1 have overcome the examiner's objection.

### ***Response to Arguments - Claim Rejections 35 USC § 112***

*Response to Arguments – WRITTEN DESCRIPTION (35 USC 112, first paragraph)*

Applicant's arguments, see page 12-13 and Claim amendments, filed REMARKS, received 1/23/2007, with respect to claim 7 have been fully considered and

are not persuasive. The rejection of Claim 7 under 35 USC 112, first paragraph (Written Description), cannot be withdrawn at this time, for the reasons of record, namely that the disclosure is not sufficient to show that a skilled artisan would recognize that the applicant was in possession of the claimed invention genus of polynucleotides encompassed by this claim including a considerable number of nucleotides varying in the length of the nucleic acids, the degree of homologies among the sequences, and the biological activities of the encoded polypeptides, which may or may not be involved in the function of IkbNS. This genus also embraces sub-sequences that are unknown and include unsequenced polynucleotides, whose function is yet to be determined. The applicant asserts that the "specification adequately demonstrates Applicant' possession of ***an isolated nucleic acid*** comprising ***a sequence*** that hybridizes under high stringency to SEQ ID NO:1" (emphasis added. REMARKS, page 13). The examiner agrees with the applicant that the specification shows possession of a single isolated nucleic acid. A single species of a genus is insufficient to adequately describe the genus. Claim 7, however, is broadly drawn such that it applies to a large number of unknown nucleic acids.

Therefore, the rejection of claim 7 under 35 USC 112, first paragraph (Written Description) is maintained.

*Response to Arguments – ENABLEMENT (35 USC 112, first paragraph)*

Applicant's arguments, see page 13-16 and Claim amendments, filed REMARKS, received 1/23/2007, with respect to claim 7 have been fully considered and are not persuasive.

*The applicant arguments are as follows:*

The applicant disputes that there would be undue experimentation required to make and use the invention. The applicant asserts that because hybridization is routine in the art the examiner's argument that there would be unknown polypeptides isolated during the hybridization technique. None of the arguments disputing the validity of the Wolcott and Gress references overcomes the examiner's assertion that unpredictable and unknown polynucleotides will be isolated during hybridization under high stringency conditions.

Although the amendment to claim 7 has reduced the scope of nucleic acids encompassed by the original version claim 7, the genus of nucleic acids encompassed by the currently amended claim 7 still encompasses a potentially huge number polynucleotides. The nucleic acids might also encompass very large nucleic acids that hybridize under highly stringent conditions only over a short range near one end of both sequences. In this case, there would be a very low level of homology between the two sequences, despite high stringency hybridization. The limitation by hybridization is obviously generic to a considerable number of nucleotides varying in the length of the nucleic acids, the degree of homologies among the sequences, and the biological

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activities of the encoded polypeptides, which may or may not be involved in the function of IkbNS. Furthermore, some of the nucleic acids that fit within the genus of Claim 7 would not be homologues of SEQ ID NO:1. In fact, despite hybridizing under high stringency conditions, these molecules would be structurally and functionally unrelated to SEQ ID NO:1-2. Sequences which fit into this class of unrelated molecules would require further research in order for an artisan to learn how to use them. Furthermore, the artisan would have no reason to make such sequences.

The applicant also asserts that that "a person of skill in the art would know how to make and use an isolation nucleic acid that hybridizes and high stringency to SEQ ID NO:1 and a nucleic acid sequence that encodes SEQ ID NO:2, wherein the isolated nucleic acid encodes a polypeptide that reduces NFkB-sensitive reporter activity in Cos cells." If the claim were actually drawn so narrowly, it would not be as easily rejected under the enablement statute as the currently worded claim is. Claim 7 is currently written in a Markush form where the isolated nucleic acid hybridizes to any of the three options 7i, 7ii, or 7iii. The possibility for numerous nucleic distinct nucleic acids to hybridize with 7i or 7ii, particularly, permits the examiner to maintain his rejection based on lack of possession of the large genus of unknown nucleic acids.

Therefore, the rejection of claim 7 under 35 USC 112, first paragraph (enablement) is hereby maintained.



***Response to Arguments - Claim Rejections 35 USC § 102***

Applicant's arguments, see page 16-17, REMARKS, received 1/23/2007 have been fully considered and are found to be partially persuasive.

The applicant argues that there is no anticipation by Lamerdin et al to reject claims 1-2 and 4-5 under 35 U.S.C. 102(b). The examiner maintains that the arguments of the applicant are insufficient to overcome the rejection of claims 1-2 and 4-5.

The examiner believes that there was some confusion for the applicant about which portion of claim 1 was being rejected in his Office Action (mailed 9/19/2006). On page 11, line 11 of the Office Action, the examiner wrote, "meets the limitations of claim 1-i". Whether by human error or an overly active spell checker, the examiner's intended language of "meets the limitations of claim 1-ix" was not included in the Office Action. Although the examiner did not identify this oversight before mailing the Office Action, the examiner included rejection arguments directed to the limitations of claim 1-ix. Although there are some applicant remarks directed to the limitations of claim 1-i, the applicant also submitted remarks that addressed the examiner's rejection of claim 1-ix. It should be noted that the applicant's amendment to claim 1 (received 1/23/2007), has changed the optional limitation discussed above from 1-ix to 1-v.

In the initial rejection of claim 1, the examiner writes "Claim 1 is directed to 'an isolated nucleic acid molecule consisting of a nucleic acid sequence selected from...a nucleic acid that encodes SEQ ID NO:2.'" (page 11, Office Action, mailed 9/19/2007). The examiner argues that "the Lamerdin et al. sequence teaches all of the 15000 bases of SEQ ID NO:1....Many molecules can encode SEQ ID NO:2. For example, a cDNA

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molecule can encode SEQ ID NO:2. However, the instant Specification (page 2, lines 20-27) indicates that SEQ ID NO:1 can encode SEQ ID NO:2. Since SEQ ID NO:1 contains introns and encodes SEQ ID NO:2, the GenBank sequence AD000864 which comprises SEQ ID NO:1 that is capable of encoding SEQ ID NO:2" (page 11, Office Action, mailed 9/19/2007). The examiner reasserts that the sequence taught by Lamerdin et al. teaches an isolated nucleic acid molecule consisting of a nucleic acid sequence selected from...a nucleic acid that encodes SEQ ID NO:2. Furthermore, the sequence taught by Lamerdin et al. teach an isolated nucleic acid molecule consisting of a nucleic acid sequence selected from...a portion of SEQ ID NO:1 which is at least about 500 nucleotides in length. Lamerdin et al. teach also teach a portion of the complement of SEQ ID NO:1 which is at least about 500 nucleotides in length.

The applicant disagrees with the examiner's analysis and explains that Lamerdin et al. (GenBank Accession No. AD000864) discloses a 39,146 base, single-stranded DNA sequence which encodes APLP1. The applicant argues that the Lamerdin sequence does not comprise SEQ ID NO:1, but instead teaches the reverse complement of SEQ ID NO:1. GenBank DNA sequence submissions only include a single strand. Nevertheless, the reverse complement of a GenBank DNA sequence is inherent in the sequence submitted. Such a sequence does encode SEQ ID NO:2. It is for this reason that the examiner originally rejected claim 1 and maintains his rejection of claim 1.

The examiner agrees with the applicant that Lamerdin et al. sequence (GenBank Accession No. AD000864) does not teach to an isolated nucleic acid molecule

consisting of a nucleic acid sequence SEQ ID NO:1 or the complement thereof. The examiner did not and does not believe that claim 1 can be rejected on the basis of the limitations of claim 1-i. The typo described above that may have lead the applicant to believe otherwise.

Nevertheless, the rejection of claims 1-2 and 4-5 under 35 USC 102(b) is maintained.

The applicant argues that there is no anticipation by Rosen et al to reject claims 7-8 under 35 U.S.C. 102(b). Based on the amendments to claims 7-8, the examiner finds the arguments persuasive, and withdraws his rejection of claims 7-8, based on Rosen et al. under 35 U.S.C. 102(b).

***Response to Arguments - Claim Rejections 35 USC § 103***

Applicant's arguments filed 23 January 2007 (REMARKS, page 17-20) directed to the rejection of claims 1-6 have been fully considered and they are found partially persuasive.

The applicant argues that a person of skill in the art would not "at once envisage" Applicant's claimed invention. The applicant also argues that the examiner used impermissible hindsight in rejecting the instant invention. Furthermore, the applicant

argues that Lamerdin et al. does not teach an isolated nucleic acid consisting of a nucleic acid that encodes SEQ ID NO:2.

The "at once envisage" phrase is applied (in MPEP 2131.02) in species-genus situations where one species is disclosed and other alternative species are not specifically named, but the genus is small enough that a skilled artisan would understand the other members of the genus. Although this argument does not exactly apply to the examiner's 103 argument, he does understand why the applicant has chosen to argue this point. In the "reasonable expectation of success" section of the 103 rejection (Office Action, page 15, filed 9/29/2006), the examiner states that the sequences of Lamerdin "can be substituted for any functions that the sequences of the instant application are put to use." The idea of functional equivalency could be viewed as implying Markush-like species. The examiner takes heed of the applicant's argument in this matter and modifies his 103 rejection, as described below.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). However, the examiner also understands why the applicant would choose to suggest the use of "impermissible hindsight" in suggesting motivation to make

modifications in a "DNA sequence that contains all of the coding sequences of IkbNS" since IkbNS was unknown to Lamerdin et al. Again, the examiner takes heed of the applicant's argument in this matter and modifies has 103 rejection, as described below.

Regarding the applicant's argument that Lamerdin et al. does not teach an isolated nucleic acid consisting of a nucleic acid that encodes SEQ ID NO:2, the examiner disagrees. It is here that the modification to the 103 rejection will become clear. Since the examiner continues to assert that the Lamerdin sequence (GenBank sequence AD000864) inherently teaches the reverse complement of GenBank sequence AD000864, which comprises SEQ ID NO:1, which encodes SEQ ID NO:2 (page 11, Office Action, mailed 9/19/2007). The limitations of claims 1-2 and 4-5 are satisfied by this teaching. The limitations of claim 1, which are directed to 500 nucleotide portions of SEQ ID NO:1 are similarly satisfied by the Lamerdin sequence. There are no other functional equivalents taught by the Lamerdin et al. sequence within the claims as currently amended that are obvious over claims 1-2 and 4-5. The examiner hopes that the scope of the obviousness rejection is clearer to the applicant.

In addition, the applicant did not argue the aspect of the obviousness 103 rejection directed to claims 3 and 6, wherein the nucleic acid is RNA. So the examiner assumes that the applicant has accepted that RNA corresponding to Claim 1-v and claim 4, are an obvious over the Lamerdin et al. DNA sequence.

Therefore, the rejection of claims 1-6 under 35 USC 103(a) is maintained.

Applicant's arguments filed 23 January 2007 (REMARKS, page 17-20) directed to the rejection of claims 10-12 have been fully considered and they are not persuasive.

As described above, in both the 102 and 103 sections, the examiner reasserts that the Lamerdin et al. sequence does indeed satisfy the limitations of claims 1 and 4. Essentially, the vectors of claims 10-11 comprise the nucleic acids of claims 1 or 4. The cell of claim 12 comprises the vector of claim 11. Because there is sufficient motivation to combine the vectors and cells of Liu et al. with the Lamerdin sequence and the examiner holds that the Lamerdin sequence meets the limitations of the isolated nucleic acids sequences described in claim 10, the rejection of claims 10-12 under 35 USC 103(a) is maintained.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 7-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Dias Neto et al. 2000. Proc. Natl. Acad. Sci. U.S.A. 97 (7), 3491-3496.

Claims 7-8 are directed to isolated nucleic acid molecules and probes that hybridize under high stringency conditions to SEQ ID NO:1.

Dias Neto et al. teach a 182 nucleotide DNA sequence that has 100% identity to the reverse complement of SEQ ID NO:1 at nucleotides 5364-5545. This sequence would hybridize under high stringency conditions to SEQ ID NO:1 or could be used as a probe for SEQ ID NO:1.

Accordingly, Dias Neto et al. anticipate the instant claims.

***Claim Rejections - 35 USC § 112, 1<sup>st</sup> paragraph (Written Description)***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. **This is a new matter rejection.** The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 1 recites "at least about 500 nucleotides in length" in parts iii and iv. The specification does not have support for this language. On page 3, lines 3-4 of the specification, there are references to "about 200 to 500 nucleotides in length" and "greater than 500 nucleotides in length". Neither of these phrases is equivalent to the language of claim 1.

The methodology for determining adequacy of Written Description to convey that applicant was in possession of the claimed invention includes determining whether the application describes an actual reduction to practice, determining whether the invention is complete as evidenced by drawings or determining whether the invention has been set forth in terms of distinguishing identifying characteristics as evidenced by other descriptions of the invention that are sufficiently detailed to show that applicant was in possession of the claimed invention (*Guidelines for Examination of Patent Applications under 35 USC § 112, p 1 "Written Description" Requirement*; (Federal Register/Vol 66, No. 4, Friday, January 5, 2001; II Methodology for Determining Adequacy of Written Description (3.)).

Considering the potentially large numbers of polynucleotides encompassed by these claims, the disclosure is not sufficient to show that a skilled artisan would recognize that the applicant was in possession of the claimed invention (genus) commensurate to its scope at the time the application was filed.



***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

No claims are allowed.

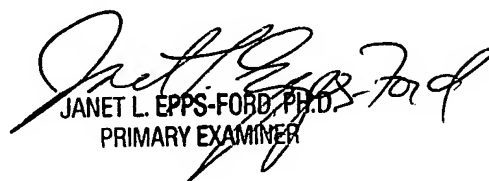
***Examiner Contact Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Scott Long** whose telephone number is **571-272-9048**. The examiner can normally be reached on Monday - Friday, 9am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Joseph Woitach** can be reached on **571-272-0739**. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Scott Long  
Patent Examiner  
Art Unit 1633

  
JANET L. EPPS-FORD, PH.D.  
PRIMARY EXAMINER